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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKES *et al.*

Appl. No. 09/583,200

Filed: May 30, 2000

For: **HLA Class I A2 Tumor Associated  
Antigen Peptides and Vaccine  
Compositions**

Confirmation No. 1443

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0150002/HCC/PAC

**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

In accordance with 37 C.F.R. 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Documents AM1, AP1, and AN2 cited on form PTO 1449:

Document AM1, Patent No. EP 0 226 513 is in the French language. It is believed that AM1 discloses HIV peptide derivatives. An English language abstract of document AM1 is attached as Document AS25;

Document AP1, Patent No. WO 92/21033 is in the German language. It is believed that AP1 discloses peptides which bind MHC class I and class II molecules. An English language abstract of document AP1 is located on page one of the document and another English language abstract is attached as Document AT25;

Document AN2, Patent No. WO 94/11738 is in the German language. It is believed that AN2 discloses peptides which bind MHC class I and class II molecules. An English

language abstract of document AN2 is located on page one of the document and another English language abstract is attached as Document AR26.

The Examiner is referred to the following list of related, co-pending patent applications:

U.S. Patent Application No. 08/205,713, filed March 4, 1994, inventor Grey, submitted herewith as Document AR29;

U.S. Patent Application No. 08/344,824, filed November 23, 1994, inventors Sette *et al.*, submitted herewith as Document AS29;

U.S. Patent Application No. 08/347,610, filed December 1, 1994, inventors Kubo *et al.*, submitted herewith as Document AT29;

U.S. Patent Application No. 08/452,843, filed March 30, 1995, inventors Sette *et al.*, submitted herewith as Document AR30;

U.S. Patent Application No. 09/017,524, filed February 3, 1998, inventors Kubo *et al.*, submitted herewith as Document AS30.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson  
Agent for Applicants  
Registration No. 47,473

Date: 2/19/03

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FORM PTO-1449  <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 2060.0150002/HCC/PAC		APPLICATION NO. 09/583,200	
		APPLICANT Fikes et al.			
		FILING DATE May 30, 2000		GROUP 1644	

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,200,320	04/06/1993	Sette et al.			12/07/1987
	AB1	5,503,829	04/02/1996	Ladant et al.			11/07/1994
	AC1	5,585,461	12/17/1996	Townsend et al.			03/24/1994
	AD1	5,662,907	09/02/1997	Kubo et al.			01/25/1994
	AE1	6,034,214	03/07/2000	Boon et al.			12/13/1994
	AF1	6,077,519	06/20/2000	Storkus et al.			01/15/1997
	AG1	2002/0168374 A1	11/14/2002	Kubo et al.			03/20/1997
	AH1	2002/0177694 A1	11/28/2002	Sette et al.			02/03/1998
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 044 710 A1	01/27/1982	Europe			Yes No
	AM1	EP 0 226 513 A1	06/24/1987	Europe			Yes X No
	AN1	WO 92/02543 A1	02/20/1992	WIPO			Yes No
	AO1	WO 92/12996 A2	08/06/1992	WIPO			Yes No
	AP1	WO 92/21033 A1	11/26/1992	WIPO			Yes X No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Aichele, P., et al., "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide," <i>J. Exp. Med.</i> 171:1815-1820, Rockefeller University Press (1990)
AS	1	Alexander, J., et al., "Derivation of HLA-A11/K <sup>b</sup> Transgenic Mice. Functional CTL Repertoire and Recognition of Human A11-Restricted CTL Epitopes," <i>J. Immunol.</i> 159:4753-4761, The American Association of Immunologists (November 1997)
AT	1	Bergmann, C.C., et al., "Differential Effects of Flanking Residues on Presentation of Epitopes from Chimeric Peptides," <i>J. Virol.</i> 68:5306-5310, American Society for Microbiology (August 1994)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 93/03764 A1	03/04/1993	WIPO			Yes No
	AM2	WO 94/03205 A1	02/17/1994	WIPO			Yes No
	AN2	WO 94/11738 A1	05/26/1994	WIPO			Yes X No
	AO2	WO 94/20127 A1	09/15/1994	WIPO			Yes No
	AP2	WO 96/03140 A1	02/08/1996	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Bertoni, R., et al., "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis," <i>J. Clin. Invest.</i> 100:503-513, The American Society for Clinical Investigation, Inc. (August 1997)
AS	2	Bertoni, R., et al., "Human Class I Supertypes and CTL Repertoires Extend to Chimpanzees," <i>J. Immunol.</i> 161:4447-4455, American Association of Immunologists (October 1998)
AT	2	Bjorkman, P.J., et al., "Structure of the human class I histocompatibility antigen, HLA-A2," <i>Nature</i> 329:506-512, Macmillan Publishers, Ltd. (1987)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Bjorkman, P.J., et al., "The foreign antigen binding site and T cell recognition regions of class I histocompatibility antigens," <i>Nature</i> 329:512-518, Macmillan Publishers, Ltd. (1987)
AS	3	Buus, S., et al., "Autologous Peptides Constitutively Occupy the Antigen Binding Site on Ia," <i>Science</i> 242:1045-1047, American Association for the Advancement of Science (1988)
AT	3	Carreño, B.M., et al., "HLA-B37 and HLA-A2.1 molecules bind largely nonoverlapping sets of peptides," <i>Proc. Natl. Acad. Sci. USA</i> 87:3420-3424, National Academy Press (1990)

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	4	Corr, M., et al., "Endogenous Peptides of a Soluble Major Histocompatibility Complex Class I Molecule, H-2L <sup>d</sup> : Sequence Motif, Quantitative Binding, and Molecular Modeling of the Complex," <i>J. Exp. Med.</i> 176:1681-1692, Rockefeller University Press (December 1992)
AS	4	De Bruijn, M.L.H., et al., "Peptide loading of empty major histocompatibility complex molecules on RMA-S cells allows the induction of primary cytotoxic T lymphocyte responses," <i>Eur. J. Immunol.</i> 21:2963-2970, VCH Verlagsgesellschaft mbH (1991)
AT	4	Del Val, M., et al., "Efficient Processing of an Antigenic Sequence for Presentation by MHC Class I Molecules Depends on Its Neighboring Residues in the Protein," <i>Cell</i> 66:1145-1153, Cell Press (1991)

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	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Deres, K., et al., "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine," <i>Nature</i> 342:561-564, Macmillan Publishers, Ltd. (1989)
AS	5	DiBrino, M., et al., "HLA-A1 and HLA-A3 T Cell Epitopes Derived from Influenza Virus Proteins Predicted from Peptide Binding Motifs," <i>J. Immunol.</i> 151:5930-5935, The Association of Immunologists (December 1993)
AT	5	DiBrino, M., et al., "Endogenous peptides bound to HLA-A3 possess a specific combination of anchor residues that permit identification of potential antigenic peptides," <i>Proc. Natl. Acad. Sci. USA</i> 90:1508-1512, National Academy Press (February 1993)

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Ding, Y.-H., et al., "Two Human T Cell Receptors Bind in a Similar Diagonal Mode to the HLA-A2/Tax Peptide Complex Using Different TCR Amino Acids," <i>Immunity</i> 8:403-11, Cell Press (April 1998)
AS	6	Eisenlohr, L.C., et al., "Flanking Sequences Influence the Presentation of an Endogenously Synthesized Peptide to Cytotoxic T Lymphocytes," <i>J. Exp. Med.</i> 175:481-487, The Rockefeller University Press (February 1992)
AT	6	Engelhard, V.H., "Structure of peptides associated with MHC Class I molecules," <i>Curr. Opin. Immunol.</i> 6:13-23, Current Biology, Ltd. (February 1994)

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	AN						Yes No
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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	2	Falk, K., et al., "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules," <i>Nature</i> 351:290-296, Macmillan Publishers, Ltd. (1991)
AS	2	Falk, K., et al., "MHC peptide motif register. Peptide motifs of HLA-B35 and -B37 molecules," <i>Immunogenetics</i> 38:161-162, Springer-Verlag (April 1993)
AT	2	Falk, K., et al., "Allele-specific peptide ligand motifs of HLA-C molecules," <i>Proc. Natl. Acad. Sci. USA</i> 90:12005-12009, National Academy Press (December 1993)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	8	Falk, K., et al., "Pool sequencing of natural HLA-DR, DQ, and DP ligands reveals detailed peptide motifs, constraints of processing, and general rules," <i>Immunogenetics</i> 39:230-242, Springer-Verlag (February 1994)
AS	8	Falk, K., et al., "Peptide motifs of HLA-A1, -A11, -A31, and -A33 molecules," <i>Immunogenetics</i> 40:238-241, Springer-Verlag (July 1994)
AT	8	Foon, K.A., "Biological Response Modifiers: The New Immunotherapy," <i>Cancer Res.</i> 49:1621-1639, American Association for Cancer Research (1989)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

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AR	9	Geysen, H.M., et al., "Cognitive Features of Continuous Antigenic Determinants," <i>J. Mol. Recognit.</i> 1:32-41, Heyden & Sons, Ltd. (1988)
AS	9	Guo, H.-C., et al., "Different length peptides bind to HLA-Aw68 similarly at their ends but bulge out in the middle," <i>Nature</i> 360:364-366, Macmillan Publishers, Ltd. (November 1992)
AT	9	Henderson, R.A., et al., "HLA-A2.1-Associated Peptides from a Mutant Cell Line: A Second Pathway of Antigen Presentation," <i>Science</i> 255:1264-1266, American Association for the Advancement of Science (March 1992)

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>10</u>	Hill, A., et al., "Characterization of two Epstein-Barr virus epitopes restricted by HLA-B7," <i>Eur. J. Immunol.</i> 25:18-24, VCH Verlagsgesellschaft mbH (January 1995)
AS	<u>10</u>	Hunt, D.F., et al., "Characterization of Peptides Bound to the Class I MHC Molecule HLA-A2.1 by Mass Spectrometry," <i>Science</i> 255:1261-1263, American Association for the Advancement of Science (March 1992)
AT	<u>10</u>	Ishioka, G.Y., et al., "Utilization of MHC Class I Transgenic Mice for Development of Minigene DNA Vaccines Encoding Multiple HLA-Restricted CTL Epitopes," <i>J. Immunol.</i> 162:3915-3925, The American Association of Immunologists (April 1999)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>11</u>	Jameson, S.C., and Bevan, M.J., "Dissection of major histocompatibility complex (MHC) and T cell receptor contact residues in a K <sup>b</sup> -restricted ovalbumin peptide and an assessment of the predictive power of MHC-binding motifs," <i>Eur. J. Immunol.</i> 22:2663-2667, VCH Verlagsgesellschaft mbH (October 1992)
AS	<u>11</u>	Jardetzky, T.S., et al., "Identification of self peptides bound to purified HLA-B27," <i>Nature</i> 353:326-329, Macmillan Publishers, Ltd. (1991)
AT	<u>11</u>	Kannagi, M., et al., "Target Epitope in the Tax Protein of Human T-Cell Leukemia Virus Type I Recognized by Class I Major Histocompatibility Complex-Restricted Cells," <i>J. Virol.</i> 66:2928-2933, American Society for Microbiology (May 1992)

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	AO						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>12</u>	Kast, W.M., et al., "Protection against lethal Sendai virus infection by in vivo priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," Proc. Natl. Acad. Sci. USA 88:2283-2287, National Academy Press (1991)
AS	<u>12</u>	Kast, W.M., et al., "Strict peptide length is not required for the induction of cytotoxic T lymphocyte-mediated antiviral protection by peptide vaccination," Eur. J. Immunol. 23:1189-1192, VCH Verlagsgesellschaft mbH (May 1993)
AT	<u>12</u>	Krieger, J.I., et al., "Single amino acid changes in DR and antigen define residues critical for peptide-MHC binding and T cell recognition," J. Immunol. 146:2331-2340, American Association of Immunologists (1991)

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AS	<u>13</u>	Maryanski, J.L., et al., "Synthetic peptides as antigens and competitors in recognition by H-2-restricted cytolytic T cells specific for HLA," <i>J. Exp. Med.</i> 167:1391-1405, Rockefeller University Press (1988)
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AR	<u>15</u>	Pamer, E.G., et al., "Precise prediction of a dominant class I MHC-restricted epitome of <i>Listeria monocytogenes</i> ," <i>Nature</i> 353:852-855, Macmillan Publishers, Ltd. (1991)
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AT	<u>15</u>	Parker, K.C., et al., "Peptide Binding to HLA-A2 and HLA-B27 Isolated from <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 267:5451-5459, American Society for Biochemistry and Molecular Biology, Inc. (March 1992)

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AR	<u>16</u>	Parker, K.C., et al., "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2," <i>J. Immunol.</i> 149:3580-3587, American Association of Immunologists (December 1992)
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AR	<u>17</u>	Reddehase, M.J., et al., "A pentapeptide as minimal antigenic determinant for MHC class I-restricted T lymphocytes," <i>Nature</i> 337:651-653, Macmillan Publishers, Ltd. (1989)
AS	<u>17</u>	Romero, P., et al., "H-2K <sup>d</sup> -restricted Antigenic Peptides Share a Simple Binding Motif," <i>J. Exp. Med.</i> 174:603-612, Rockefeller University Press (1991)
AT	<u>17</u>	Rothbard, J.B., "Major histocompatibility complex-peptide interactions," <i>Curr. Opin. Immunol.</i> 2:99-105, Current Biology, Ltd. (1989)

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AR	<u>18</u>	Rötzschke, O., et al., "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T cells," <i>Nature</i> 348:252-254, Macmillan Publishers, Ltd. (1990)
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AT	<u>18</u>	Rötzschke, O., and Falk, K., "Naturally-occurring peptide antigens derived from the MHC class-I-restricted processing pathway," <i>Immunol. Today</i> 12:447-455, Elsevier Science Publishers, Ltd. (1991)

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AT	<u>23</u>	Whitton, J.L., et al., "Molecular Analyses of a Five-Amino-Acid Cytotoxic T-Lymphocyte (CTL) Epitope: an Immunodominant Region Which Induces Nonreciprocal CTL Cross-Reactivity," <i>J. Virol.</i> 63:4303-4310, American Society for Microbiology (1989)

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AT	<u>24</u>	Zhang, Q-J., et al., "An HLA-A11-specific motif in nonamer peptides derived from viral and cellular proteins," <i>Proc. Natl. Acad. Sci. USA</i> 90:2217-2221, National Academy Press (March 1993)

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AR	<u>26</u>	Dialog File 351, Accession No. 9888606, Derwent WPI English language abstract for WO 94/11738.
AS	<u>26</u>	Boel, P., et al., "BAGE: a New Gene Encoding an Antigen Recognized on Human Melanomas by Cytolytic T Lymphocytes," <i>Immunity</i> 2:167-175, Cell Press (February 1995)
AT	<u>26</u>	Boon, T., "Tumor Antigens Recognized by Cytolytic T Lymphocytes: Present Perspectives for Specific Immunotherapy," <i>Intl. J. Cancer</i> 54:177-180, Wiley-Liss, Inc. (May 1993)

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FORM PTO-1449 <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 2060.0150002/HCC/PAC	APPLICATION NO. 09/583,200
		APPLICANT Fikes et al.	
		FILING DATE May 30, 2000	GROUP 1644

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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## FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	27	Brasseur, R., "Differentiation of Lipid-associating Helices by Use of Three-dimensional Molecular Hydrophobicity Potential Calculations," <i>J. Biol. Chem.</i> 266:16120-16127, The American Society for Biochemistry (1991)
AS	27	Gambacorti-Passerini, C., et al., "Mapping of HLA Class I Binding Motifs in Forty-four Fusion Proteins Involved in Human Cancers," <i>Clin. Cancer Res.</i> 3:675-683, American Association for Cancer Research (May 1997)
AT	27	Kamashima, I., et al., "The Multi-epitope Approach for Immunotherapy for Cancer: Identification of Several CTL Epitopes from Various Tumor-Associated Antigens Expressed on Solid Epithelial Tumors," <i>Human Immunol.</i> 59:1-14, Elsevier Science Inc. (January 1998)

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>28</u>	Knuth, A., et al., "Cellular and humoral immune responses against cancer: implications for cancer vaccines," <i>Curr. Opin. Immunol.</i> 3:659-664, Current Biology (1991)
AS	<u>28</u>	Toes, R.E.M., et al., "Enhancement of Tumor Outgrowth Through CTL Tolerization After Peptide Vaccination Is Avoided by Peptide Presentation on Dendritic Cells," <i>J. Immunol.</i> 160:4449-4456, The American Association of Immunologists (May 1998)
AT	<u>28</u>	van der Bruggen, P., et al., "A peptide encoded by human gene MAGE-3 and presented by HLA-A2 induces cytolytic T Lymphocytes that recognize tumor cells expressing MAGE-3," <i>Eur. J. Immunol.</i> 24:3038-3043, VCH Verlagsgesellschaft mbH (December 1994)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>29</u>	Copy of co-pending U.S. Patent Application 08/205,713, inventors Grey, H.M., filed March 4, 1994 (NOT PUBLISHED).
AS	<u>29</u>	Copy of co-pending U.S. Patent Application 08/344,824, inventors Sette, A. and Sidney, J., filed November 23, 1994 (NOT PUBLISHED).
AT	<u>29</u>	Copy of co-pending U.S. Patent Application 08/347,610, inventors Kubo et al., filed December 1, 1994 (NOT PUBLISHED).

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>30</u>	Copy of co-Pending U.S. Patent Application No. 08/452,843, inventors Sette, A. and Sidney, J., filed March 30, 1995 (NOT PUBLISHED).
AS	<u>30</u>	Copy of co-Pending U.S. Patent Application No. 09/017,524, inventors Kubo et al., filed February 3, 1998 (NOT PUBLISHED).
AT		

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